DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 15, 2014

Ethicon Incorporated
Mr. Peter Cecchini
Fellow, Regulatory Affairs
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K141776
Trade/Device Name: STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: July 22, 2014
Received: July 23, 2014

Dear Mr. Cecchini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141776

Device Name
STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device

Indications for Use *(Describe)*
STRATAFIX™ Symmetric PDS™ Plus Devices are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary is provided below:

Device Common Name: Suture, Surgical, Absorbable, Polydioxanone

Device Proprietary Name: STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device

Submitter:
Ethicon Inc.
P.O. Box 151
Route 22 West
Somerville, NJ 08876
USA

Contact:
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Date Prepared: September 15, 2014

Classification Regulation: Absorbable Polydioxanone Surgical Suture, Class II, 21 CFR 878.4840

Panel: General and Plastic Surgery Devices

Product Code: **NEW**

Predicate Device: STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device

Indication for Use:

STRATAFIX™ Symmetric PDS™ Plus Devices are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.

Device Description:

STRATAFIX Symmetric PDS Plus Devices are prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_x$. STRATAFIX Symmetric PDS Plus Devices will contain IRGACARE®‡ MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360 µg /m. STRATAFIX Symmetric PDS Plus Devices are dyed with D&C Violet No. 2 (21CFR§ 74.3602) at a maximum of 0.15% w/w. STRATAFIX Symmetric PDS Plus Devices consists of an absorbable monofilament thread with unidirectional barbs, with a surgical needle attached at one end and a fixation tab at the other. The barbs and fixation tab design allow for tissue approximation without the need to tie surgical knots.

Performance Data:

Performance testing to demonstrate equivalence was conducted using performance testing-bench models and performance testing-animal models. Testing results are summarized as follows.

- Performance Testing-Bench Models:

    1. Tissue Holding Strength – The results of the tissue holding testing verify the integrity and adequacy of the STRATAFIX Symmetric PDS PLUS device performance in a simulated wound closure and support substantial biomechanical equivalence to the predicate device.
    2. Initiation Strength- The results of the initiation strength testing verify the integrity and adequacy of the device during application at the proximal end of a simulated wound closure compared to the predicate device.
    3. Cyclic Compression- The results of the cyclic compression testing verify the integrity and adequacy of the device when subjected to a cyclic compressive load on a simulated wound closure compared to the predicate device.
    4. Usability Study- The results of this study were used to confirm the usability of the device and to refine the Instructions for Use.

- Performance Testing-Animal Models:
    1. Preclinical Survival Study – The results of the survival study demonstrated substantial equivalence in wound approximation and healing to the predicate device.

Substantial Equivalence:

STRATAFIX Symmetric PDS Plus Knotless Tissue Control Devices has the same intended use, design, materials and technological characteristics as the predicate device. Modification to the labeling is the only difference from the predicate device.

Conclusions:

The STRATAFIX Symmetric PDS Plus Device has the same intended use and identical indications for use as the predicate device. In comparison, the technological characteristics are the same. The differences in labeling (IFU) between the proposed device and the predicate device raise no new questions of safety or effectiveness. STRATAFIX Symmetric PDS PLUS Devices met all testing criteria to demonstrate substantial equivalence to the predicate device.

** Trademark*
IRGACARE®‡ MP (triclosan) “Registered Trademark of BASF Group”